UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,978	06/15/2000	Varghese John	00270-US-NEW	8679

21835 7590 06/25/2002

ELAN PHARMACEUTICALS, INC.
INTELLECTUAL PROPERTY DEPARTMENT
800 GATEWAY BOULEVARD
SOUTH SAN FRANCISCO, CA 94080

EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	11

DATE MAILED: 06/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/594,978	Applicant(s) JOHN ET AL.	
	Examiner David Lukton	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *2,3,7,17,18,21,22,24-46,48,49,53,63,64,67 and 68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,8-16,19,20,23,47,50-52,54-62,65,66 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Applicants' election of Group 2 (claims 1, 4-6, 8-16, 19, 20, 47, 50-52, 54-62, 65, 66, limited to G2) as is the elected specie (the compound of example 23, page 28).

Claims 23 and 69 are examined in this Office action; in addition, claims 1, 4-6, 8-16, 19, 20, 47, 50-52, 54-62, 65, 66 are examined in part.

*

The specification is objected to.

On page 32 of the specification, a "URL" is present. As this may be transitory, it should be eliminated from the specification.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 47 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 47 is drawn to a "pharmaceutical" composition. This term implies an assertion of therapeutic efficacy, which is not in evidence. It may well be the case that the following

claim is enabled:

> *A method of inhibiting the formation of amyloid beta protein comprising administering to a mammal in need thereof a compound according to claim 1 for a time and under conditions effective to inhibit beta-secretase.*

However, treatment of Alzheimer's disease is another matter. It is not established that formation of the amyloid beta protein will occur to a sufficient degree to be of consequence, or that even if the claimed compounds could completely prevent all cleavage of *beta*-amyloid precursor protein, that therapeutic benefit would accrue to the patient.

This ground of rejection can be overcome by deleting the term "pharmaceutical" from line 1 of claim 47.

*

Claims 1, 4-6, 8-16, 19, 20, 23, 47, 50-52, 54-62, 65, 66, 69 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- In claim 1, variable "A" is bonded to a nitrogen atom. However, nitrogen forms three bonds, not two. Accordingly a substituent (e.g., hydrogen) is missing from the nitrogen atom. A related issue is that variable "G" can be a single nitrogen atom, resulting in the same defect.

- In claim 1, the following is recited:

  R is H, C_{1-6}-alkyl, phenyl or benzyl ...
  ... independently selected from ... -COOH, -

  Note that following the "-COOH,", a hyphen is present. This hyphen should be moved to the next line, so that it is attached to something.

- Throughout claim 1, the term "including" is used in an attempt to further define the substituent in question. For example, it is recited that "R_a" can be carbamyl "including phenyl amides". As it happens, a phenyl amide is not a carbamyl group, but that is not the point. The point is that if the term "phenyl amide" were subgeneric to the term "carbamyl", the claim would still be indefinite, although for a different reason. The term "including" fails to set the metes and bounds. What is suggested is that where the substituent following the word "including" is properly subgeneric to the term for which applicants are seeking clarification, the substituent following the word "including" should be eliminated from the independent claim and moved to a dependent claim. And those terms which are not properly subgeneric (for example, an ester is not a carbamyl group) should just be eliminated.

- In claim 1, it is recited that "B" can be "heterocyclylic". However, it would seem that the term *heterocyclic* would be sufficient.

- In claim 15, line 1, the following is recited:

  "Bis"

  Here, there should be a space between "B" and "is"

- Clarification is sought with regard to claim 20. It is recited that "A" and "B" are both selected according to claim 15. Is this intended?

- The clarity of claim 47 would be improved if the first line of the claim were amended to recite the following,

  A composition comprising a compound of formula 1 in combination with a pharmaceutically acceptable diluent...

  and if the last line of the claim were amended to recite the following:

  ...or a pharmaceutically acceptable salt or ester thereof.

- In claim 60, the standard "selected from the group consisting of" language should be adopted.

*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Majer (WO 97/30072).

Majer discloses (page 37) compound 6. This anticipates claim 1 when the substituent variables correspond as follows:

A is t-butyloxycarbonyl

B is OMe

R1 is isopropyl

R2 is benzyl

Claim 1 does not explicitly recite that "A" can be t-butyloxycarbonyl. However, claim 1 does permit "A" to be either of the following: "alkylacyloxy" or "carboxyalkyloxy" (in original claim 1, this is recited on page 73, lines 16-20). The terms "alkylacyloxy" and "carboxyalkyloxy" are somewhat ambiguous. However, according to one interpretation, either of these terms could encompass tBoc.

Thus, the claim is anticipated.

*

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

See, for example, the sequence on page 51.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800